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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of William D. Picking et al — Art Unit 1645
Serial No. 09/830,026
Filed October 20, 2001
Confirmation No. 9340
For METHOD FOR THE PRODUCTION OF PURIFIED INVASIN PROTEIN AND USE THEREOF
Examiner S. Devi

May 1, 2003

RESPONSE TO RESTRICTION REQUIREMENT

TO THE ASSISTANT COMMISSIONER FOR PATENTS,

SIR:

In response to the restriction requirement dated April 1, 2003, Applicants elect Group III (claims 13-18, 21, 22, 25, and 101-103) for examination, subject to the following traverse.

Reconsideration of the restriction requirement is respectfully requested in regards to Groups I-V. Groups I and II relate to a purified recombinant invasin protein comprising the amino acid sequence SEQ ID NO:1 (Group I) or SEQ ID NO:2 (Group II). Group III relates to a method for the production of a purified recombinant invasin protein. Groups IV and V relate to a method for eliciting an immune response in an animal. The method involves administering to an animal an adjuvant composition comprising a purified recombinant invasin protein of claim 1, that comprises an amino acid sequence, SEQ ID NO:1 (Group IV) or SEQ ID NO:2 (Group V).

In applying PCT Rule 13, the Office has indicated that the common special technical feature of the listed inventions is the purified recombinant invasin protein as recited in claim 1, but that "such a product was already taught or suggested in the prior art," and is therefore not a unifying feature. In support of this, the Office cites Picking,

et al. (*Protein Expr. Pur.*, 8:401-08, 1996) and Markart, et al. (*Infect. Immun.*, 64:4182-87, 1996).

Applicants respectfully submit that the purified recombinant invasin protein as set forth in claim 1 is a special technical feature. Claim 1 is for "A composition comprising a recombinant invasin protein of at least 95% purity." However, neither of the cited references teaches or suggests a recombinant invasin protein of at least 95% purity. Marquart, et al. describe the purification of recombinant IpaC,[1] but do not specifically indicate the degree of purity. Picking, et al. describe the purification of recombinant IpaB and IpaC, stating, "[r]ecombinant IpaB and IpaC were purified to greater than 90% homogeneity...."[2] Picking, et al., however, do not give any examples of IpaB or IpaC of at least 95% purity, and do not indicate that the purification process they used is capable of producing IpaC of at least 95% purity. As such, it is submitted that a recombinant invasin protein of at least 95% purity, as described in claim 1, is a unifying special technical feature. Since Groups I and II and Group III are products and method of producing the products, and Groups IV and V are methods of using a purified recombinant invasin protein of claim 1,[3] applicants respectfully request rejoinder of Groups I-V.

Furthermore, applicants respectfully submit that rejoinder of both Group I and Group II does not impose a serious burden on the Office.[4] Groups I and II both

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[1] Marquart, et al., *Infect. Immun.*, 64:4182-87, 4183 (1996).

[2] Picking, et al., *Protein Expr. Pur.*, 8:401-08, 405 (1996).

[3] *See* 37 C.F.R. § 1.475(b), "An international or a national stage application covering claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:...(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product."

[4] *See* MPEP § 803, "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions."

encompass claims 4, 31, and 54, and differ only in regards to amino acid sequence, SEQ ID NO:1 (Group I) or SEQ ID NO:2 (Group II). In regards to nucleotide sequences, MPEP § 803.04 states, "It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." In light of this, applicants submit that the examination of two amino acid sequences does not impose a serious burden on the Office. A similar situation exists for Groups IV and V, which both relate to claim 85 and differ only in regards to amino acid sequence, SEQ ID NO:1 (Group IV) and SEQ ID NO:2 (Group V).

In light of the foregoing, applicants respectfully request reconsideration of the restriction requirement in regards to Groups I-V.

The Commissioner is hereby authorized to charge any underpayment of government fees to Deposit Account No. 19-1345.

Respectfully submitted,

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